REMARKS

I. Background

The claimed invention of the present application is directed to topically-applicable photodynamic medicaments or topical pharmaceutical compositions for photodynamic treatment that have a halogenated xanthene as the active component. For the reasons stated in Amendment C, filed April 17, 2003, as well as those presented infra, Applicants respectfully submit that no prior art anticipates nor renders obvious the claimed invention, as delineated by the amended set of claims provided herein. Accordingly, each of the Examiner's rejections in the Final Rejection are traversed herein as explained in depth infra.

First, however, Applicants believe that it will be beneficial to briefly examine the claimed subject matter in order to compare this with the teachings of Goers and Neckers.

The pending, amended independent claims of the present application are directed to *topically-applicable photodynamic medicaments* or *topical pharmaceutical compositions* for photodynamic treatment, wherein the *sole active component* is a halogenated xanthene. In order to make this clear, Applicants have amended each of the independent claims to recite a medicament or pharmaceutical composition *consisting of a halogenated xanthene* as the active component.

Further, the language of the amended independent claims makes it clear to one of ordinary skill in the art that the claimed medicaments and pharmaceutical compositions are drugs that control or cure disease by virtue of their intrinsic pharmacologic properties. Although they *could* be used in combination with other agents, or their active component conjugated to other agents, such medicaments *do not require* such combination or conjugation and are not claimed as such in the amended independent claims. Thus, the claimed photodynamic medicaments and pharmaceutical

compositions are capable of affecting their desired therapeutic effect alone, without requirement of combination with, or conjugation to, additional agents.

Applicants will now address each of the Examiner's rejections in the order in which they appear in the Final Rejection.

II. Claim Rejections - 35 U.S.C. §102

The Examiner rejects Claims 1-10, 12-19, 21, 23-25, 27-30, 32-34 and 36-38 under 35 U.S.C. §102(b) as being anticipated by Goers et al. This rejection is respectfully traversed.

In support of this rejection, the Examiner states that "the teachings of Goers et al. clearly state that the photosensitizers, including in particular Rose Bengal (col. 20, lines 50-55), are disclosed as being therapeutic agents ... independent of the antibody attachment (see col. 21, lines 9-13)." While Applicants agree that Goers discloses that Rose Bengal is a photosensitizer, they refute the relevance of these cited passages, and of Goers in general, to the claimed invention for at least the following reasons.

(1) While Goers discloses Rose Bengal as a photosensitizer, there is no disclosure or suggestion therein of photodynamic medicaments consisting of Rose Bengal as the active component.

In the specific passage cited by the Examiner, Goers describes certain "therapeutic agents" that may be attached to antibodies or antibody fragments to form conjugate compositions suitable for in vivo administration (for example, see Claim 1 in Goers). These include "photochemical compounds" (col. 19, line 57) and "photosensitizers" (col. 20, lines 48-64, which includes Rose Bengal as a listed photosensitizer). Since this disclosure of Rose Bengal is provided in the context

of a description of "therapeutic agents" that may be used in conjugate form (i.e., upon attachment to antibodies or antibody fragments), it does not comprise a disclosure or suggestion of Rose Bengal, by itself, as a photodynamic medicament.[1] Tellingly, Goers does not claim photosensitizers alone, or any medicaments consisting substantially of any photosensitizer alone. Instead, Goers claims photosensitizers conjugated with antibodies or antibody fragments, as evidenced by Claim 1 therein. The reason for this becomes clear upon examination of the Background of the Invention in Goers.

In the Background of the Invention, Goers teaches that photodynamic therapy (i.e., PDT, which is refered to therein as "photoradiation therapy") has tremendous promise, but also states that it is plagued by a number of fundamental unresolved problems that make it undesirable:

> "2.4. PHOTORADIATION THERAPY
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> "Advances in optics technology and greater understanding of photochemistry and photobiology have raised interest in the technique of photoradiation therapy for treating a variety of disease states....
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> "Despite promising developments, however, photochemicals (e.g., hematoporphyrin and other photosensitizers) have several disadvantages for clinical use. First, there is great potential for damage to normal tissue if the areas adjacent to the tumor are not protected.... A second disadvantage is that patients receiving photoradiation therapy are generally extremely sensitive to sunlight.... Third, the dosage levels of photosensitizer required for therapy are very high and may have a negative effect on normal tissue." (col. 5, line 50 - col. 6, line 21 in Goers)

This passage clearly teaches that *existing* "photochemicals ... have several disadvantages" (i.e., lack of specificity, prolonged photosensitivity, and toxicity at the required, high dosage levels) that make their use disadvantageous and impractical. Goers then proceeds to teach that these disadvantages

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[1]As explained herein, the teachings in Goers are clearly directed to agents in conjugate form. As a result, one skilled in the art would not think that col. 21, lns. 9-13 cited by the Examiner discloses therapeutic agents independent of an antibody attachment as a topical medicament, as claimed in the present application.

can be overcome by designing *new photosensitizers* having improved specificity for diseased tissue:

> "The ideal photosensitizer *should be designed* so that it has greater tumor specificity, requiring a lower therapeutic dose level, hence mitigating the deleterious effect of higher doses. Greater tumor specificity leads to more efficient localization to the site of action and less opportunity for dispersal throughout the body.
>
> Mew et al. have demonstrated the use of *monoclonal antibody conjugated* via carbodiimide bonding to hematoporphyrin as an anti-cancer agent...." (col. 5, line50 - col. 6, line 30 in Goers, emphasis added)

In particular, in this passage Goers advances the idea that the ideal approach for solving the inherent shortcomings of "photoradiation therapy" is to improve targeting of photosensitizers using *photosensitizer conjugates*. Goers' specific prescription for execution of this solution is then taught in the immediately succeeding section:

> "3. SUMMARY OF THE INVENTION
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> "According to the general method of the present invention, a therapeutic agent is covalently attached to an antibody or antibody fragment." (col. 6, lines 33-36 in Goers)

Thus, Goers teaches that the way to improve PDT is to attach therapeutic agents (i.e., photosensitizers) to antibodies or antibody fragments. This approach, as described in Goers, is purported to overcome the failings recited in the reference as being inherent among existing photosensitizers.

Goers' teachings with respect to conjugate agents are made unambiguous by the Detailed Description of the Invention therein, which includes the passages cited by the Examiner:

> "5.3. THERAPEUTIC AGENTS

> "Antibodies may be attached to any therapeutic agent .... As used herein, the term "therapeutic agent" includes chemical modifications and derivatives of therapeutic agents which substantially retain their biological activity....
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> "The therapeutic agent to be attached to an antibody for use in a delivery system is selected according to the purpose of the intended application.... Such therapeutic agents may include, for example, ... photochemical compounds. Table I lists some of the pharmaceutical agents that may be employed in the herein described invention....
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> "TABLE I EXAMPLES OF THERAPEUTIC AGENTS FOR ANTIBODY-MEDIATED DELIVERY" (col. 19, lines 23-65 in Goers)

Here Goers teaches that "therapeutic agents" are to be attached to an antibody for "antibody-mediated delivery." Suitable therapeutic agents include photochemical compounds, as described in Goers in the passage immediately following Table I:

> "According to one embodiment of the present invention, photochemicals including photosensitizers and photothermolytic agents may be used as therapeutic agents. Efficient photosensitizers include, but are not limited to ... rose bengal.... (col. 20, lines 48-55 in Goers)

Thus, Goers teaches that one of the antibody-therapeutic agent conjugates in the reference comprises Rose Bengal attached to an antibody or antibody fragment.[2]

Such a conjugate agent (i.e., Rose Bengal covalently attached to an antibody or antibody fragment) is not Rose Bengal: it is "Rose Bengal Antibody Conjugate" or "Rose Bengal Antibody-Fragment Conjugate."

The fact that Goers is concerned exclusively with conjugate agents is clear from the description of the disclosed method in "Photoradiation Therapy" therein:

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[2] Applicants note that Goers never discusses possible use of Rose Bengal in a non-conjugate form.

"5.5.1. PHOTORADIATION THERAPY

"One type of *photoradiation* therapy (also referred to in this context as *photoimmunotherapy*) which advantageously *uses the antibody-therapeutic agent conjugates* of this invention encompasses the treatment of disorders by combining the phototoxic effects of certain compounds and the site specific attachment of the antibody to a target site." (col. 28, lines 43-51 in Goers, emphasis added)

Thus, Goers discloses use of Rose Bengal as a photosensitizer, but solely in the context of its use as a component of a conjugate agent that is formed upon attachment of Rose Bengal to antibodies or antibody fragments. To reinforce this point, Goers even coins a new term, "photoimmunotherapy," to distinguish the described invention from prior art.

In the aforementioned passages Goers clearly teaches that photosensitizers, alone in their non-conjugate form, have negligible therapeutic value. These purported shortcomings include (a) lack of specificity, (b) prolonged photosensitivity, and (c) toxicity at the required dosage levels (see col. 5, line50 - col. 6, line 30 in Goers). In doing so, Goers teaches away from the claimed invention and the core teachings of the present application by discouraging use of any non-conjugate photosensitizers, including Rose Bengal.

In contrast, the teachings in the present application show that certain photosensitizer medicaments, including those consisting of Rose Bengal (or another halogenated xanthene) as the sole photoactive component, afford significant therapeutic value, and *are not plagued* by (a) poor specificity, (b) prolonged photosensitivity, or (c) toxicity at the required dosage levels. These features are clearly described throughout the specification, for example:

"In general, the halogenated xanthenes are characterized by a *low dark cytotoxicity* (toxicity to cells or tissues in the absence of photoactivation), *high light cytotoxicity* (toxicity to cells or tissues upon photoactivation) .... This makes such chemical

agents, and in particular medicaments formulated from such agents, excellent PDT agents for the treatment of human and animal tissues.

"It is thus a preferred embodiment of the present invention that a topically-applicable medicament be produced that contains, as an active ingredient at a concentration of from greater than approximately 0.001% to less than approximately 20%, at least one halogenated xanthene." (p. 6, lines 6-15 in the present application)

This passage teaches that, absent any requirement of conjugation to antibodies or antibody fragments, the halogenated xanthenes (such as Rose Bengal) are useful therapeutic ingredients when incorporated into topically-applicable photodynamic medicaments. A number of specific examples of photodynamic use are thereafter provided in the present application, including, for example, the following:

In an example of a preferred embodiment of this method of treatment or medical use, applicants have found that application of a cream or solution containing Rose Bengal at a concentration of approximately 0.1% W/V to persistent leg ulcers, followed, after a latency period of 0-72 hours, and more preferably 0-1 hour, by illumination with approximately 10 to 200 J/cm^2 of continuous or pulsed green light in the 500-600 nm band, leads to substantial or complete healing of such persistent leg ulcers, with little or no side effects in surrounding tissue." (p. 13, lines 8-13 of the present application)

Thus, in contrast to the teachings in Goers, which require conjugation of Rose Bengal to an antibody or antibody fragment in order to avoid alleged toxicity and to achieve specificity for diseased tissue, the teachings of the present application show that non-conjugate Rose Bengal is, in fact, free of such requirements and shortcomings.

Accordingly, whereas Goers teaches about certain therapeutic agents comprising Rose Bengal conjugates, the present application teaches and claims that such conjugates are unnecessary.

Moreover, whereas Goers teaches that photosensitizers are intrinsically dangerous and poorly targeted (i.e., that they lack of specificity; elicit prolonged photosensitivity; and are intrinsically

toxic), the present application teaches that photodynamic medicaments based on the halogenated xanthenes (such as non-conjugate Rose Bengal) afford a high degree of safety and specificity.

The fact is that the two teachings are discussing and claiming different compounds and medicaments: Goers is describing agents comprised of Rose Bengal antibody conjugates while the present application is describing and claiming medicament consisting substantially of Rose Bengal.

In focusing on conjugates, Goers has completely missed the exquisite properties of Rose Bengal (which, as disclosed in the present application, make such conjugates unnecessary and irrelevant). Accordingly, Goers does not disclose or suggest the claimed invention. Instead of describing the presently claimed photodynamic medicaments consisting of Rose Bengal as the active component, Goers merely notes the well known properties of Rose Bengal as a chemical that exhibits photosensitizer properties, and including such photosensitizing chemicals in a range of components to be incorporated into conjugate agents.

Any semantic overlap between the respective teachings in Goers and those of the present application is explained by the duality of meaning for the term "photosensitizer."

(2) "Photosensitizer" is a broad term; Goers' use of this term does not anticipate nor render obvious the claimed topical photodynamic medicaments.

Goers uses the term "photosensitizer" in the context of photosensitizer-antibody conjugate agents, wherein such conjugate agents are purported to comprise a novel and useful therapeutic entity. In this regard, Goers attributes certain chemical and physical properties to Rose Bengal, but does not disclose the use of Rose Bengal itself in, or as, a functioning medicament. In fact, while Goers' use of the term is consistent with the inherent breadth of meaning for photosensitizer, the

reference does not anticipate or render obvious the claimed invention, since a photosensitizer can be: (a) a compound that photosensitizes a material; or (b) a pharmaceutical (i.e., drug or medicament) containing one or more photosensitizing compound. Goers' attributes the former meaning to Rose Bengal, but it is only in the antibody-conjugate form that the reference attributes the latter meaning.[3]

To begin a careful examination of the relevant terminology, Applicants note that an on-line dictionary of the English language[4] defines *photosensitize* in the following terms:

> "to make sensitive to the influence of radiant energy and especially light"

Accordingly, a *photosensitizer* is something (such as a chemical compound) that makes something else (such as cancerous tissue) sensitive to the effects of radiant energy (such as light). A more specialized reference, The Photonics Dictionary[5], defines *photosensitizer* in the following terms:

> "A substance that increases a material's sensitivity to electromagnetic radiation. In photodynamic therapy, a drug used to render a target tissue sensitive to laser light."

Hence, Merriam-Webster and The Photonics Dictionary agree that a photosensitizer is a substance (i.e., typically a chemical compound) that increases the sensitivity of a material (i.e., tissue) to the

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[3] In fact, as Applicants have noted supra, Goers teaches that existing, non-conjugate photosensitizers, which according to the specification in Goers includes Rose Bengal, are unsuitable for use as active ingredients in medicaments due to alleged poor specificity, prolonged photosensitivity, and toxicity (see col. 5, line 50- col. 6, line 21).

[4] Merriam-Webster OnLine, at www.m-w.com; relevant portions attached as Exhibit A.

[5] The Photonics Dictionary, 49th International Edition (2003), Laurin Publishing; relevant portion attached as Exhibit B.

effects of light. Moreover, in the special context of photodynamic therapy, a photosensitizer can be a "drug" used to render tissue sensitive to light.

Thus, as noted supra, "photosensitizer" has dual meaning: (a) a compound that renders a material (such as tissue) sensitive to light; and (b) a drug that, upon administration, renders tissue sensitive to light.

Returning to the aforementioned on-line dictionary of the English language,[6] this reference defines *photodynamic* in the following terms:

> "of, relating to, or having the property of intensifying or inducing a *toxic reaction* to light (as in the destruction of cancer cells stained with a light-sensitive dye) in a living system" (emphasis added)

The meaning of this process is reiterated by The Photonics Dictionary, which defines *photodynamic therapy* as follows:[7]

> "A medical technology that uses lasers or other light sources in combination with *photosensitizing drugs* to treat cancerous tumors." (emphasis added)

Together, these definitions confirm that "photosensitizer" has a dual meaning:

- at the most basic level, a photosensitizer is a chemical compound that increases sensitivity of a material (such as a cancerous tumor) to applied light;

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[6] Merriam-Webster OnLine, *ibid.*

[7] The Photonics Dictionary, *ibid.*

- in the context of *photodynamic therapy*, photosensitizers are drugs that are administered in some manner in order to achieve photosensitization of tissue to be treated.[8]

Thus, a photosensitizing compound (i.e., a photosensitizer) is a crucial component of the photosensitizing drug used for PDT (i.e., also called a photosensitizer), but such compound is not, by itself, a photosensitizing drug.

At the core of Applicants distinction regarding this issue is the fact that Goers attributes "chemical compound" photosensitizer properties to Rose Bengal, while at the same time teaching that Rose Bengal itself is not appropriate for use as a photosensitizing "drug" owing to the purported problems associated with existing photosensitizers. Specifically, by noting its potential use as a "chemical compound" suitable for incorporation into conjugate agents, Goers attributes specific chemical and physical properties to Rose Bengal. However, Goers fails to disclose use of non-conjugate Rose Bengal as a "drug," to do so, Goers would, at the very least, need to (a) describe how such drug would be formulated as a medicinal agent (i.e., identify the active substance and a delivery vehicle or physical form of such drug), or (b) describe how such a drug was to be used (i.e., for injection, ingestion, topical application, etc.). Goers does not describe formulation or use of any drug consisting of any non-conjugate photosensititizer, and thus does not disclose or suggest the medicaments of the present application nor the specific use of Rose Bengal claimed in the present application.

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[8] As an example of the unfortunate flexibility of the term photosensitizer, Applicants note that a photosensitizer used for photodynamic therapy must contain one or more photosensitizing compounds (which would also be referred to as photosensitizers).

(3) The medicaments described in Goers and by the present application are distinctly different.

Notably, while Goers notes certain well known properties of Rose Bengal (i.e., that it is a photosensitizing compound), the reference does not describe the claimed invention of the present application since the reference does not describe the claimed photodynamic medicament. This is clear for several reasons:

(a) the active photosensitizer ingredients are not the same. Goers teaches away from use of non-conjugate Rose Bengal, and instead prescribes use of antibody conjugates. In contrast, the present application teaches and claims that Goers' antibody conjugation is unnecessary, and that non-conjugate Rose Bengal may be successfully used as the active ingredient in certain topical photodynamic medicaments.[9]

(b) Goers does not teach the presently claimed topical medicaments, but rather medicaments for parenteral (i.e., systemic) administration. It would be clear to one of ordinary skill in the art that any parenteral medicament prepared using the teachings in Goers is not a topical medicament, as is claimed in the present application.

Moreover, since the U.S. Food and Drug Administration (FDA) strictly regulates commerce of all medicaments sold in the U.S., and requires specific labeling of such medicaments, there is no possibility for confusion of Goers' medicaments with those of the present application. Specifically,

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[9] As a litmus test of this position, Applicants note that one skilled in the art, upon reading the disclosure in Goers, would be led away from the presently claimed invention since Goers teaches that existing photosensitizing compounds, such as Rose Bengal, are intrinsically non-specific and potentially dangerous. Accordingly, Goers cannot be teaching the claimed invention of the present application.

FDA would mandate that any hypothetical medicament based on the teachings in Goers be clearly identified at least as follows:

(a) Active Ingredient: Rose Bengal Antibody Conjugate (or Rose Bengal Antibody-Fragment Conjugate); and

(b) Directions for Use: Parenteral or intravenous injection.

In contrast, any medicament based on the teachings of present application would be clearly identified at least as follows:

(a) Active Ingredient: Rose Bengal; and

(b) Directions for Use: Topical application.

Thus, whereas the teachings in Goers require:

(a) conjugation of Rose Bengal to antibodies or antibody fragments, and

(b) parenteral (i.e., systemic) administration of the resultant conjugate,

the claimed invention does not require such conjugation, and instead concerns topical, rather than parenteral, administration. Accordingly, they do not utilize the same active ingredients and are not the same medicaments.

(4) Goers does not disclose or suggest a topical medicament whereas the claimed invention is directed to a topical medicament.

Notwithstanding the aforementioned differences between the teachings in Goers and those of the present application concerning various uses of Rose Bengal and Rose Bengal conjugates, as detailed supra, Goers still fails to anticipate or render obvious the claimed invention of the present

application since the reference does not disclose or suggest any topical medicament based on any photosensitizer or photosensitizing compound.

More specifically, Goers certainly does not teach topical use of "Rose Bengal conjugate." In fact, Goers fails to use the term "topical" (or any similar or related term) anywhere in the reference's specification or claims. Instead, Goers exclusively concerns systemic administration of conjugate agents, as evidenced by the following passage:

> "5.5. USES OF ANTIBODY-THERAPEUTIC AGENT CONJUGATES
>
> "The *antibody-therapeutic agent conjugates* of the invention are useful in a variety of therapeutic in vivo applications....
>
> "Therapeutic applications center generally on treatment of various cellular disorders, including those broadly described above, by *administering an effective amount of the antibody-therapeutic agent conjugates* of the invention....
>
> "According to this aspect of the invention, the antibody or antibody fragment of the antibody therapeutic agent conjugate functions to deliver the conjugate to the target site.
>
> "In vivo administration may involve use of therapeutic agents of antibody therapeutic agent conjugates in any suitable adjuvant including serum or physiological saline, with or without another protein, such as human serum albumin.... *Route of administration* may be *parenteral*, with *intravenous administration generally preferred.*" (col. 27, line 48 - col. 28, line 42in Goers, emphasis added)

This passage makes it clear that Goers teachings are restricted solely to parenteral (i.e., systemic) administration. Goers makes no mention of any possible use of, or applicability to, topical administration of any therapeutic agent.

Parenteral administration (i.e., injection into the body), as taught in Goers, would not be readily confused with topical administration, as claimed in the present application. Moreover, knowledge of any possible use of such agents for parenteral administration would not lead one of

ordinary skill in the art to develop other, unrelated topically-applicable medicaments (such as those claimed in the present application).

The contrast between the parenteral agents described in Goers and the topically-applicable medicaments claimed in the present application is highlighted by several key passages from the specification of the present application:

> "The inherent disadvantages of various current PDT agents and medicaments containing such agents have made acceptable PDT-based treatment ... difficult or impossible. These disadvantages are particularly serious in the case of indications affecting external or internal surface or near surface tissues, where it would be desirable to have medicaments suitable for localized, selective treatment of the desired tissues." (p. 2, lines 14-18 of the present application)

Thus, the present application concerns topical medicaments that address the disadvantages of current PDT (including many of those noted in Goers) through use of new, topically-applicable forms of drug. Such medicaments are described, for example, in the following terms:

> "It is thus a preferred embodiment of the present invention that a topically-applicable medicament be produced that contains, as an active ingredient ... at least one halogenated xanthene." (p. 6, lines 13-15)
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> "Because the halogenated xanthenes and their derivatives are, in general, solids in their pure form, it is preferred that, for proper delivery to desired tissues, such agents be formulated in appropriate delivery vehicles.... Specifically, such formulations are preferred so as to facilitate agent contact with, and delivery to, desired tissues to be treated.
>
> "It is thus a further preferred embodiment of the present invention that at least one halogenated xanthene or halogenated xanthene derivative be formulated as a medicament in a topically-applicable form, such as in a liquid, semisolid, solid or aerosol delivery vehicle.... this vehicle may, in addition to the at least one halogenated xanthene or halogenated xanthene derivative, include various builders, stabilizers, emulsifiers or dispersants, preservatives, buffers, electrolytes, and tissue penetrating or softening agents. Such components of the delivery vehicle may be present as the primary component ... or as a minor component that serves in an adjuvant role in agent delivery." (p. 8, line 17 - p. 9, line 9)

Such details clearly describe a topically-applicable medicament. Moreover, such details and medicaments are clearly well outside the teachings in Goers.

A final salient example of the fundamental differences of the respective teachings in Goers and that claimed and taught in the present application is illustrated by Table 2 of the present application. This table contains detailed data concerning not only formulation of topical medicaments but their respective performance when applied topically to live skin. Such detail (in fact, such considerations regarding formulation and topical delivery in general) are completely absent from Goers.

Accordingly, the systemic agents disclosed in Goers are completely unrelated to the topical medicaments claimed in each of the amended independent claims of the present application.

(5) Goers concerns antibody and antibody-fragment conjugates; the amended claims of the present application do not.

In order to advance the prosecution of this application, Applicants have amended Claims 5 and 25, deleting all reference to "antibodies" from the claimed subject matter. Such amendment removes any potential for superficial similarity between the teachings in Goers and the claimed invention.

Therefore, for at least the above-stated reasons, Applicants respectfully submit that the pending, amended claims of the present application are not disclosed or suggested in Goers but are patentable thereover. Hence, it is requested that this rejection be withdrawn.

III. Claim Rejections - 35 U.S.C. §103

The Examiner also has also reiterated her rejection of Claims 16-19, 30 and 34 under 35 U.S.C. 103 as obvious over Goers et al. in view of Neckers. This rejection is also respectfully traversed.

As stated supra, Goers fails to teach or suggest a topically-applicable medicament, which is the fundamental subject matter of each of the rejected claims. Similarly, Neckers also fails to teach such a medicament. Thus, irrespective of any teachings in Neckers concerning certain physical properties of Rose Bengal, any hypothetical combination of these references would fail to draw one of ordinary skill in the art to the present invention. For instance, using Neckers' teachings that Rose Bengal absorbs light at 549 nm does not cure the fundamental failure of the teachings in Goers, which states:

> "In vivo administration may involve use of therapeutic agents of antibody therapeutic agent conjugates in any suitable adjuvant including serum or physiological saline, with or without another protein, such as human serum albumin.... Route of administration may be parenteral, with intravenous administration generally preferred." (col. 28, lines 33-42)

Parenteral administration (i.e., injection into the body), as taught in Goers, would not be readily confused with topical administration, as recited in each independent claim of present application.

Moreover, a skilled practitioner would not be induced to attempt topical administration through hypothetical combination of the teachings in Goers and Neckers. Adding the use of light having a wavelength between approximately 500 nm and 600 nm to the teachings in Goers cannot cure the shortcomings in Goers concerning route of administration, nor would it otherwise draw one to the claimed invention.

Accordingly, for at least these reasons, the cited references fail to disclose or suggest the claims of the present application. Therefore, it is respectfully requested that this rejection be withdrawn.

IV. Conclusion

For at least the above-stated reasons, it is respectfully submitted that the claims of the present application are in an allowable form and are patentable over the cited references. Accordingly, it is requested that the application now be allowed.

If any fee should be due for this response, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

Date: October 2, 2003

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